

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 20 MAY 2005  
PCT/JP2003/014812



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Applicant's or agent's file reference PH-1902-PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/014812	International filing date (day/month/year) 20 November 2003 (20.11.2003)	Priority date (day/month/year) 21 November 2002 (21.11.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/54, 9/10, C07K 16/40, C12N 1/15, 1/19, 1/21, 5/10, C12Q 1/48, A61K 38/45, A61P 35/00		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.	
<input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).	
These annexes consist of a total of _____ sheets.	
3. This report contains indications relating to the following items:	
I <input checked="" type="checkbox"/>	Basis of the report
II <input type="checkbox"/>	Priority
III <input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV <input type="checkbox"/>	Lack of unity of invention
V <input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI <input type="checkbox"/>	Certain documents cited
VII <input type="checkbox"/>	Certain defects in the international application
VIII <input type="checkbox"/>	Certain observations on the international application

Date of submission of the demand 20 November 2003 (20.11.2003)	Date of completion of this report 01 April 2004 (01.04.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/014812

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP03/14812

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	11-17	YES
	Claims	1-10, 18-20	NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

**2. Citations and explanations****Document 1: WO, 02-46426, A2**

Document 1 discloses DME8, one of drug-metabolizing enzymes cloned from a human, of which the amino acid sequence is represented by SEQ ID NO.: 8 and the base sequence is represented by SEQ ID NO.: 21. It also describes that DME8 is highly homologous with N acetylglucosamine transferase of human origin. In the claims, a gene encoding DME8, a vector, recombinant cells, an antibody to DME8, a probe for detecting polynucleotide hybridizing a DME8 gene, and the like are mentioned.

The amino acid sequence of DME8 shown in document 1 has an about 86% identity with the SEQ ID NO.: 2 of the invention of the present application (by the use of the alignment parameters shown in the description of the present application), and the base sequence of DME8 has an about 96% identity with the SEQ ID NO.: 1 (the portion corresponding to ORF) of the invention of the present application.

Thus, the subject matters of claims 1-10 and 18-20 of the present application are the same as the inventions of document 1 and do not appear to be novel.

The involvement of the sugar chain structure in the transmission of signals to cancerous cells was well known to a person skilled in the art before the date of priority of the present application and so a person skilled in the art could have easily arrived at the possibility of using, as an anticancer agent, an antibody to a protein having a high homology with N acetylglucosamine transferase and screening compounds which interact with DME8. Furthermore, the invention of the present application does not produce a greater effect than that expected by a person skilled in the art.

Accordingly, the subject matters of claims 11-17 of the present application could have been easily conceived of by a person skilled in the art on the basis of the invention of document 1 and so do not appear to involve an inventive step.